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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,722	11/30/2001	David W. Morris	529452000123	3325

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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/997,722	MORRIS ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: Morris et al.

Claims 1-19 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to one recombinant nucleic acid comprising a nucleotide sequence selected from the group outlined in Tables 1-50, classified in class 536, subclass 23.1.

(Upon election of group I, Applicant must further choose a single nucleotide sequence, as each nucleic acid sequence is an independent group, not a species. Applicant is reminded that any claims not reading on the elected sequence will be withdrawn as drawn to non-elected inventions.)

II. Claim 5, drawn to one recombinant protein comprising an amino acid sequence encoded by a nucleic acid sequence comprising a sequence selected from the group outlined in Tables 1-50, classified in class 530, subclass 350.

(Upon election of group II, Applicant must further choose a single nucleotide sequence, as each nucleic acid sequence is an independent group, not a species. Applicant is reminded that any

claims not reading on the elected sequence will be withdrawn as drawn to non-elected inventions.)

III. Claims 6 and 7, drawn to a method of screening drug candidates, classified in class 435, subclass 4.
(Upon election of group III, Applicant must further choose a single nucleotide sequence, as each nucleic acid sequence is an independent group, not a species. Applicant is reminded that any claims not reading on the elected sequence will be withdrawn as drawn to non-elected inventions.)

IV. Claims 8 and 9, drawn to a method of screening for a bioactive agent capable of binding or modulating the activity of a CA protein (CAP), classified in class 435, subclass 4.
(Upon election of group IV, Applicant must further choose a single nucleotide sequence, as each nucleic acid sequence is an independent group, not a species. Applicant is reminded that any claims not reading on the elected sequence will be withdrawn as drawn to non-elected inventions.)

V. Claim 10, drawn to a method of evaluating the effect of a candidate carcinoma drug, classified in class 436, subclass 64.

(Upon election of group V, Applicant must further choose a single nucleotide sequence, as each nucleic acid sequence is an independent group, not a species. Applicant is reminded that any claims not reading on the elected sequence will be withdrawn as drawn to non-elected inventions.)

VI. Claim 11 and 18, drawn to a method of diagnosing carcinoma or a propensity of carcinoma, classified in class 424, subclass 9.1.

(Upon election of group VI, Applicant must further choose a single nucleotide sequence, as each nucleic acid sequence is an independent group, not a species. Applicant is reminded that any claims not reading on the elected sequence will be withdrawn as drawn to non-elected inventions.)

VII. Claim 12 and 14, drawn to a method for inhibiting the activity of or neutralizing the effect of a CA protein (CAP), classified in class 435, subclass 4.

(Upon election of group VII, Applicant must further choose a single nucleotide sequence, as each nucleic acid sequence is an independent group, not a species. Applicant is reminded that any claims not reading on the elected sequence will be withdrawn as drawn to non-elected inventions.)

VIII. Claim 13, drawn to a method of treating carcinomas comprising administering to a patient an inhibitor of a CA protein (CAP), classified in class 514, subclass 1.

(Upon election of group VIII, Applicant must further choose a single nucleotide sequence, as each nucleic acid sequence is an independent group, not a species. Applicant is reminded that any claims not reading on the elected sequence will be withdrawn as drawn to non-elected inventions.)

IX. Claim 15, drawn to a polypeptide which specifically binds to a protein encoded by one nucleic acid comprising a nucleic acid selected from the group outlined in Tables 1-50, classified in class 530, subclass 350.

(Upon election of group IX, Applicant must further choose a single nucleotide sequence, as each nucleic acid sequence is an independent group, not a species. Applicant is reminded that any claims not reading on the elected sequence will be withdrawn as drawn to non-elected inventions.)

X. Claim 16, drawn to an antibody which specifically binds to a protein encoded by one nucleic acid comprising a nucleic acid selected from the group outlined in Tables 1-50, classified in class 530, subclass 387.1.

(Upon election of group X, Applicant must further choose a single nucleotide sequence, as each nucleic acid sequence is an independent group, not a species. Applicant is reminded that any claims not reading on the elected sequence will be withdrawn as drawn to non-elected inventions.)

XI. Claim 17, drawn to a biochip, classified in class 536, subclass 24.3.
(Upon election of group XI, Applicant must further choose a single nucleotide sequence, as each nucleic acid sequence is an independent group, not a species. Applicant is reminded that any claims not reading on the elected sequence will be withdrawn as drawn to non-elected inventions.)

XII. Claim 19, drawn to a method of determining CA gene copy number comprising adding an CA gene probe to a sample of genomic DNA from an individual, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I, II, and IX-XI represent distinct products, as outlined in the instant specification. Group I is drawn to a nucleic acid, group II is drawn to a

recombinant protein, group IX is drawn to a polypeptide, group X is specifically drawn to an antibody, and group XI is drawn to a biochip. The nucleic acid in group I, the recombinant protein in group II, the polypeptide in group IX, the antibody in group X, and the biochip in group XI represent chemically distinct inventions. Searching and examining each of these groups together would invoke a serious search burden on the examiner.

The DNA of group I is related to the protein of group II by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and polynucleotides are not coextensive. The inventions of groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate database. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequences of interest there may be

journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. In addition, the claims include 70 distinct sequences inclusive of various complements and fragments. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above: furthermore, a search of the nucleic acid molecules of claim I would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of group II. As such, it would be burdensome to search the inventions of groups I and II.

The polypeptide of Groups II and IX and the antibody of group X are patentably distinct for the following reasons:

While the inventions of groups II and IX and X are all polypeptides, in this instance the polypeptides of group II represent proteins encoded by a nucleic acid sequence comprising a nucleic acid sequence selected from Table I, whereas the polypeptide of group IX represents any polypeptide capable of binding a protein from group II, whereas the polypeptide of group X encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining

regions (CDR) that function to bind an epitope. Thus the polypeptides of group II, the polypeptides of group IX, and the antibodies of group X are structurally distinct molecules; any relationship between a polypeptide of group II and IX and an antibody of group X is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

In this case, the polypeptides of group II encompass large molecules which contain potentially hundreds of regions to which an antibody may bind, whereas the antibody of group X is defined in terms of its binding specificity to a small structure within the sequences of the protein. Additionally, even though polypeptides from group IX and antibodies from group X can both bind polypeptides from group II, polypeptides from group IX could be short amino acid sequences which are structurally vastly different from antibodies of group X. Furthermore, searching the inventions of group II, group IX, and group X would impose a serious search burden. The inventions have separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group X. Furthermore, antibodies or polypeptides which bind to an epitope of a polypeptide of group II may be known even if a polypeptide of group II is novel. In addition, the technical literature search for the polypeptides of group II,

polypeptides of group IX, and the antibody of group X are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotide of group I, and the antibody of group X are patentably distinct for the following reasons:

The antibody of group X includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDRs). Polypeptides, such as the antibody of group X, which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group I will not encode an antibody of group X, and the antibody of group X cannot be encoded by a polynucleotide of group I. Therefore, the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group I and group X would impose a serious search burden since a search of the polynucleotides of

group I would not be used to determine the patentability of any antibody of group X, and vice-versa.

The inventions of groups III-VIII and XI represent materially distinct methods. Group III is drawn to a method of screening drug candidates, group IV is drawn to a method of screening for a bioactive agent capable of binding or modulating the activity of CAP, group V is drawn to a method of evaluating a drug, group VI is drawn to a method of diagnosing, group VII is drawn to a method of inhibiting the activity of or neutralizing the effect of CAP, group VIII is drawn to a method of treating carcinomas, and group XI is drawn to a method of determining a gene copy number. Each group differs in objectives, method steps, and chemically distinct reagents to accomplish the objectives. Searching all the groups with all the different objectives, method steps, and reagents would invoke a high burden or search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of

right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

Gary B. Nickol

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PRIMARY EXAMINER